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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,379	12/09/2003	Barton F. Haynes	1579-871	2849

23117 7590 03/27/2007

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EXAMINER	
KIM, YUNSOO	
ART UNIT	**PAPER NUMBER**
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/730,379	HAYNES, BARTON F.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/20/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4 and 6-20* is/are pending in the application.

4a) Of the above claim(s) *10-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-9,20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 3, 4, 6-9 and 20 are under consideration in this application.

2. In view of Applicants amendment to the specification and claims, the following rejections remain.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 3 stands rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of enhancing an immune response with a polypeptide consisting of the extracellular domain of K12 as identified by SEQ ID NO:1, does not reasonably provide enablement for any method of enhancing an immune response consisting any "portion" of any K12, any peptide 99% homologous to extracellular domain of K12, any extracellular domain of peptide 99% homologous to K12 for the reasons set forth in the office action mailed 6/20/06.

Applicant's argument filed 12/20/06 has been fully considered but was not persuasive.
Applicant argues that the claim as amended to recite sequence homology of 99% and the portion of the peptide is required to retain binding affinity for CD7.

As is well known in the art, K12 (SEQ ID NO:1) protein can be divided into 4 sections – amino acid residues 1-28 for signal sequence, amino acids 29-145 for extracellular domain (which is soluble K12), amino acids 146-167 for transmembrane region, and amino acids 168-248 for cytoplasmic domain ('030 patent, col. 5, lines 53-60, of record) and CD7 binding occurs at the extracellular domain. However, claim 3 as amended includes any portion of K12 as it does not require retaining of binding activity for CD7. Furthermore, the peptide fragment consisting of 99% homologous to the extracellular domain of K12 may not retain binding affinity to CD7 because any single amino acid change that is critical to maintain protein function requires guidance.

Ngo *et al* teach that the amino acid positions within the polypeptide/protein that can tolerate change such as conservative substitution or no substitution, addition or deletion which are critical to maintain the protein's structure will require guidance (see Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495 in particular, of record).

The art acknowledges that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases and recognized that it was unpredictable if any functional activity will be shared by two polypeptides having less than 100% identity over the full length of their sequences. Attwood (Science 2000; 290:471-473, of record) teaches that "[i]t is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences. Similarly, Skolnick et al. (Trends in Biotech. 2000; 18(1):34-39, of record) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2). Finally, even single amino acid differences can result in drastically altered functions between two proteins. For example, Metzler et al. (Nature Structural Biol. 1997; 4:527-53, of record) show that any of a variety of single amino acid changes can alter or abolish the ability of CTLA4 to interact with its ligands CD80 and CD86 (e.g., summarized in Table 2). Thus it is unpredictable if any functional activity will be shared by two polypeptides having less than 100% identity over the full length of their sequences.

In re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Since the amino acid sequence of a polypeptide determines its structural property, predictability of which amino acid fragment can retain the functional capabilities of the "portion of any K12," and "99% homologous to extracellular domain of any K12" requires knowledge and guidance with regard to which segments in the polypeptide's sequence contribute to its function.

In view of the quantity of experimentation necessary, the limited working example, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

5. Claim 3 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of a vaccine composition comprising of the polypeptide consisting of extracellular domain of K12 as identified by the SEQ ID NO:1 of the U.S. Pat. 6,350,615; however, applicant is not in possession of a vaccine composition comprising "any portion of K12", "99% homologous to extracellular domain of any K12" and "peptide at least 99% homologous to K12".

Applicant's argument filed 12/20/06 has been fully considered but was not persuasive.
Applicant argues that the claim as amended to recite sequence homology of 99% and the portion of the peptide is required to retain binding affinity for CD7. Thus, sufficient written description is provided in the specification.

The examiner's position is that there is insufficient written description encompassing "portion of any K12","95% homologous" to extracellular domain of any K12and any polypeptide comprising the extracellular domain of any K12 because any chemical or physical properties (i.e. chemical structure or specific amino acid changes lead to said function) of "any portion of K12," , 99% homologous to K12 and any polypeptide consisting of 99% homologous to extracellular domain of K12 are not set forth in the specification as filed, commensurate in scope with the claimed invention.

Claim 3 reads on any portion of K12, 99% homologous to K12 and any polypeptide consisting of 99% homologous to extracellular domain of K12 the genus encompasses the limitations is extremely large and the specification only defines soluble K12 which corresponds 29-145 amino acid residues of claimed SEQ ID NO:1.

Therefore, Applicant does not possess of scope of claimed invention. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of use.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 3, 4, 6 and 20 stand rejected under 35 U.S.C. 102 (e) as being anticipated by U.S. Pat. No. 6,762,030 B2 (of record) as is evidenced by the specification of instant application p. 6 (line 8-28) and Singh et al. (Nature Biotechnology, vol. 17, p. 1075-1081, of record) for the reasons set forth in the office action mailed 6/20/06.

Applicant's argument filed 12/20/06 has been fully considered but was not persuasive.

Applicant traverses the rejection based on that the '030 patent only describes methods of treating diseases mediated by CD7 and/or K12 using various antagonists or agonists and the claimed limitation is not taught.

However, the '030 patent teaches a method of administering **soluble K12** (corresponding extracellular domain of claimed K12 described in SEQ ID NO:1, amino acids 29-145) to mammal and the method induces interferon gamma production, NK cell proliferation (i.e. enhancing immune response, col. 9, lines 36-59, in particular), NOT the CD7 or K12 antagonists or agonists as Applicant's arguments.

The '030 patent further teaches that the molecule that promotes the interaction of CD7 and K12 enhances the immune system (col. 11, lines 8-10, in particular) and the molecules preventing CD7 and K12 are K12 antagonist such as neutralizing antibody to K12 (col. 16, lines 63-68, in particular). Thus, the administration of soluble K12 acts as agonist to the interaction of CD7 and K12 and enhances immune system.

In addition, as acknowledged in the specification of instant application on p. 1, the claimed K12 is a non-antigen specific activator of immune function , "enhancing a vaccine-induced" immune response as recited in claim 1 is an inherent property of soluble K12. Thus, prior art teachings anticipate the instant claimed invention.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1 and 7-9 stand rejected under 35. U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,762,030 B2 (of record) as is evidenced by the specification of instant application p. 6, lines 8-28 and Singh et al. (Nature Biotechnology, vol. 17, p. 1075-1081, of record) in view of Kwang (Nature Biotechnology, vol. 18, p. 1145-1146, or record) for the reasons set forth in the office action mailed 6/20/06.

Applicant's argument filed 12/20/06 has been fully considered but was not persuasive.

Applicant traverses the rejection based on that the '030 patent does not teach the claimed limitation and the combination of references is not obvious.

As discussed previously, the '030 patent teaches a method of administering **soluble K12** (corresponding extracellular domain of claimed K12 described in SEQ ID NO:1, amino acids 29-145) to mammal and the method induces interferon gamma production, NK cell proliferation (i.e. enhancing immune response, col. 9, lines 36-59, in particular), NOT the CD7 or K12 antagonists or agonists as Applicant's arguments.

The '030 patent further teaches that the molecule that promotes the interaction of CD7 and K12 enhances the immune system (col. 11, lines 8-10, in particular) and the molecules preventing CD7 and K12 are K12 antagonist such as neutralizing antibody to K12 (col. 16, lines 63-68, in particular). Thus, the administration of soluble K12 acts as agonist to the interaction of CD7 and K12 and enhances immune system.

In addition, as acknowledged in the specification of instant application on p. 1, the claimed K12 is a non-antigen specific activator of immune function, "enhancing a vaccine-induced" immune response as recited in claim 1 is an inherent property of soluble K12. Thus, the combination of reference teachings remains obvious.

10. Claims 1, 3, 4, 6 and 20 stand rejected under 35. U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,762,030 B2 (of record) as is evidenced by the specification of instant application p. 6, lines 8-28 in view of Singh et al. (Nature Biotechnology, vol. 17, p. 1075-1081, of record) for the reasons set forth in the office action mailed on 6/20/06.

Applicant's argument filed 12/20/06 has been fully considered but was not persuasive.

Applicant traverses the rejection based on that the '030 patent does not teach the claimed limitation and the combination of references is not obvious.

As discussed previously, the '030 patent teaches a method of administering **soluble K12** (corresponding extracellular domain of claimed K12 described in SEQ ID NO:1, amino acids 29-145) to mammal and the

method induces interferon gamma production, NK cell proliferation (i.e. enhancing immune response, col. 9, lines 36-59, in particular), NOT the CD7 or K12 antagonists or agonists as Applicant's arguments.

The '030 patent further teaches that the molecule that promotes the interaction of CD7 and K12 enhances the immune system (col. 11, lines 8-10, in particular) and the molecules preventing CD7 and K12 are K12 antagonist such as neutralizing antibody to K12 (col. 16, lines 63-68, in particular). Thus, the administration of soluble K12 acts as agonist to the interaction of CD7 and K12 and enhances immune system.

In addition, as acknowledged in the specification of instant application on p. 1, the claimed K12 is a non-antigen specific activator of immune function, "enhancing a vaccine-induced" immune response as recited in claim 1 is an inherent property of soluble K12. Thus, the combination of reference teachings remains obvious.

11. Claims 1 and 7-9 stand rejected under 35 U.S.C. 103(a) as being unpatentable over 6,762,030 B2 (of record) as is evidenced by the specification of instant application p. 6 (line 8-28) in view of Singh et al. (Nature Biotechnology, vol. 17, p. 1075-1081. of record) as applied to claims 1-6 above, and further in view of Kwang (Nature Biotechnology, vol. 18, p. 1145-1146, of record) for the reasons set forth in the office action mailed 6/20/06.

Applicant's argument filed 12/20/06 has been fully considered but was not persuasive.

Applicant traverses the rejection based on that the '030 patent does not teach the claimed limitation and the combination of references is not obvious.

As discussed previously, the '030 patent teaches a method of administering **soluble K12** (corresponding extracellular domain of claimed K12 described in SEQ ID NO:1, amino acids 29-145) to mammal and the method induces interferon gamma production, NK cell proliferation (i.e. enhancing immune response, col. 9, lines 36-59, in particular), NOT the CD7 or K12 antagonists or agonists as Applicant's arguments.

The '030 patent further teaches that the molecule that promotes the interaction of CD7 and K12 enhances the immune system (col. 11, lines 8-10, in particular) and the molecules preventing CD7 and K12 are K12 antagonist such as neutralizing antibody to K12 (col. 16, lines 63-68, in particular). Thus, the administration of soluble K12 acts as agonist to the interaction of CD7 and K12 and enhances immune system.

In addition, as acknowledged in the specification of instant application on p. 1, the claimed K12 is a non-antigen specific activator of immune function, "enhancing a vaccine-induced" immune response as recited in claim 1 is an inherent property of soluble K12. Thus, the combination of reference teachings remains obvious.

12. The following new ground rejection is necessitated by the Applicant's amendment filed on 12/20/06.

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out this invention.

14. Claims 1, 3, 4, 6-9 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The specification and the original claims do not provide a written description for the phrases "**consists** of a portion of K12 (SEQ ID NO:1) that includes **at least**" as in claim 1 and "**consists** of a portion of K12 (SEQ ID NO:1) or a polypeptide **at least** 99% homologous to K12 that includes at least" as in claim 2. The specification discloses the use of soluble K12 in a method of enhancing a vaccine-induced immune response and the original claim recites a polypeptide comprises the extracellular domain of K12. The scope of the claims is not commensurate with the specification and the original claims as filed.

15. No claims are allowable.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

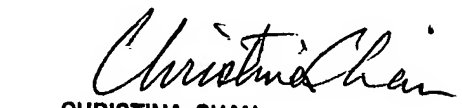
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600
March 9, 2007



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